**Purpose**

The purpose of this standard operating procedure (SOP) is to describe the process for randomization to study group for MTN-020 study participants.

**Scope**

These procedures apply to all MTN-020 staff members designated by the Site Leader/Investigator of Record to participate in the randomization process for MTN-020. Associated procedures for pharmacy staff are specified in separate SOPs that, for purposes of blinding, are on file in the study pharmacy only.

**Responsibilities**

All MTN-020 staff members, as designed by the Investigator of Record (IoR), who participate in the randomization of MTN-020 study participants, are responsible for understanding and following this SOP.

MTN-020 Site Leader/Investigator of Record (IoR) and the Study Coordinator (SC) are responsible for ensuring that relevant study staff are trained in the randomization process and follow the instructions outlined in the procedures section below.

MTN-020 Study Coordinator (SC) and the QC/QA Manager are responsible for overseeing quality control (QC) and quality assurance (QA) procedures related to this SOP.

MTN-020 Site Leader/Investigator of Record has ultimate responsibility for ensuring that all applicable MTN-020 staff members follow this SOP.

**Definitions**

For MTN-020, randomization is defined as the process according to which study participants are assigned a MTN-020 Prescription. Assignment of a Prescription is also considered the effective act of enrollment into MTN-020.

**Materials**

The following materials are used in the process of participant randomization:

* MTN-020 Randomization/Prescription Tracking Record
* MTN-020 Prescriptions

The above-listed materials will be provided by the MTN Statistical and Data Management Center (SCHARP) contained within a single hard-cover binder. Once received, this binder be stored *[insert room/office number*] in a locking file cabinet. Only [*insert staff member titles*] will have access to the locked filing cabinet containing the binder.

**PROCEDURES**

1. Pre-Randomization Enrollment Visit Procedures

On the day of enrollment, the following procedures will be performed prior to randomization, i.e., before assigning an MTN-020 Prescription to the participant:

* + Confirmation of eligibility per SOP *MTN-020-XXX*, Eligibility Determination for MTN-020
  + Collection of blood for plasma archive
  + Administration of Baseline Vaginal Practices and Baseline Behavioral Assessment CRFs
  + Administration of the ACASI Baseline Questionnaire

1. Randomization

Once procedures in Section 1.0 are completed, the participant will be assigned a prescription. [*Insert staff member titles*] are authorized to assign prescriptions. Prescriptions will be assigned by obtaining the next sequentially-numbered prescription (based on pre-printed Randomization Number) and completing the corresponding row of the MTN-020 Randomization/Prescription Tracking Record.  ***Once the prescription has been assigned as documented on the tracking record, the participant is considered enrolled into MTN-020.***

*[Include site-specific QC procedures that will be conducted on both the initial prescription and the MTN-020 Randomization/Prescription Tracking Record].*

If any problems are identified with regard to the Prescriptions (for example, a gap in Randomization Number is identified, or a Prescription does not have a Randomization Number pre-printed on it), the site will immediately contact the MTN-020 Management Team via the [mtn020mgmt@mtnstopshiv.org](mailto:mtn020mgmt@mtnstopshiv.org) email address. No further randomization procedures should occur for the current participant or any other participants until the site has been contacted by SCHARP.

All participants will be assigned to “vaginal ring”, so there is nothing to inform the participant about with regard to randomization assignment.

The site will complete the prescription as required by the instructions at the top of the prescription. Note that an authorized prescriber is required to complete the middle portion of the prescription. *[Designate staff members who are authorized prescribers. If desired, add list of authorized prescribers in an appendix.]* Once complete, the top white sheet (original) labeled “Pharmacy” will be submitted to the pharmacy and the bottom yellow copy (duplicate) labeled “Clinic” will be stored in the participant’s study notebook. If corrections are needed once the white and yellow copies have been separated, identical corrections should be made to each individual sheet. *[Designate staff responsibilities and procedures for error corrections here.]*

**List of Abbreviations and Acronyms**

SOP Standard Operating Procedure

SCHARP Statistical Center for HIV/AIDS Research and Prevention

PTID Participant identification

NCR No Carbon Required

**Attachments**

None

**References**

MTN-020 Protocol

MTN-020 Study Specific Procedures Manual, Section 04: Participant Accrual and Section 09: Study Product Considerations for Non-Pharmacy Staff

**REVISION HISTORY**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Version** | **Effective Date** | **Supersedes** | **Review Date** | Change |
| XXX-XXX | dd mmm 2012 |  |  | Initial Release |

APPROVAL

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  | Author, Author’s Title |  |  | Date |
|  |  |  |  |  |
|  | Reviewer, Reviewer’s Title |  |  | Date |